

**REMARKS**

Claim 1 has been amended by incorporating the text of claim 36 into it and by specifying that the claimed homopolymers and copolymers of ethylene oxide have a molar mass equal to or greater than 10,000 g/mol. Support for such amendments exists throughout the present specification, particularly at page 5, line 25 et seq. and page 6, line 30 et seq. No new matter has been added through these amendments.

Claims 6-11, 13, 15, 34 and 35 have been amended in a grammatical, non-limiting manner to ensure that the presence of the compounds specified in these claims is required.

The dependency of claim 39 has been changed from claim 37 (which has been canceled) to claim 1.

Claim 41 has been amended by changing the specified range from “70-300” to --70-150--. Support for this amendment exists throughout the specification, particularly at page 6, lines 11-17.

Claims 36-38 have been canceled.

Claims 1-11, 13-35 and 39-42 are currently pending.

The Office Action rejected claims 1-12 and 14-28 under 35 U.S.C. §102 as anticipated by U.S. patent 5,591,449 (“Bollens”) and/or U.S. patent 6,464,990 (“US 990”). The Office Action also rejected the pending claims under 35 U.S.C. §103 as obvious over Bollens, French patent 2,787,027 (“FR 027”), US 990, U.S. patent 6,274,150 (“US 150”) and U.S. patent 6,375,960 (“US 960”), alone, in combination and/or in further combination with, U.S. patent 6,004,566; (“Friedman”), U.S. patent 6,287,377 (“Binns”), U.S. patent 6,569,414 (“Bernecker”), U.S. patent 6,432,439 (“Suzuki”) and/or EP 728460 (“EP 460”). In view of the following comments, Applicants respectfully request reconsideration and withdrawal of these rejections.

The claimed invention relates to thickened nanoemulsions. Several different thickening agents can be used in accordance with this invention. These thickening agents must be present in a nanoemulsion thickening effective amount. Among acceptable thickening agents are homopolymers and copolymers of ethylene oxide having a molar mass equal to or greater than 10,000 g/mol. The claimed invention allows for production of thickened nanoemulsions which possess desirable transparency characteristics. None of the cited art, alone or in combination, describes or suggests this invention.

Regarding the rejections based on Bollens, the Office Action cites col. 7, lines 43-45 as disclosing that vesicles (oil globules) are 20-500 nm in size, thereby implying that this text satisfies the requirement that the claimed oil globules have a number average size of less than 100 nm. The Office Action also asserts that oil, if present in Bollens' compositions, is inside Bollens' liposomes, meaning that the oil is smaller in size than the 20-500 nm vesicles. These assertions misinterpret Bollens' disclosure.

Bollens does not relate to nanoemulsions: it relates to liposomes. Accordingly, col. 7, lines 43-45 relates to **liposome size, not oil globule size**. (See, col.4, line 36 et seq. preceding col. 7, lines 43-45).

Bollens' liposomes are dispersed within an aqueous phase. (Col. 7, lines 22-27). If oil is also present in Bollens' compositions, it is present as a separate dispersion of droplets which is stabilized by Bollens' liposomes. (Col. 7, lines 27-29). Thus, contrary to the Office Action's assertions, oil is not present inside of Bollens' liposomes. Accordingly, no conclusion can be drawn concerning the oil's size based on the size of Bollens' liposomes. In fact, when discussing the presence of an oil or oil phase, Bollens does not teach or suggest that the oil globules should be of any specific size, let alone that they should not exceed 100 nm. The Examiner (in the Advisory Action) recognizes this distinction.

Nonetheless, the Examiner holds to an unsubstantiated position that the mere happenstance that Bollens' examples use certain homogenization processes means that these examples produce nanoemulsions. Further, the Examiner states that "the use of nanoemulsions for said milks, creams and lotions is an inherent practice." (page 2 of the Advisory Action). However, the Examiner has provided no proof of this. Rather, the Examiner is using Applicants' disclosure against them. As noted by the court in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323 (CCPA 1981), the mere fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency. Inherency may not be established by probabilities or possibilities. Something that is inherent must inevitably be the result each and every time.

It is by now well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark Office. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), quoting *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967).

As noted by the Board of Patent Appeals and Interferences in *Ex parte Skinner*, 2 USPQ2d 1788, before an Examiner can switch the burden of proof of showing non-inherency to the applicant, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the functional limitation is an inherent characteristic of the prior art. In this case, the Examiner has provided no such evidence or even an explanation as to the basis for alleging that Bollens necessarily produces oil-in-water nanoemulsions with each and every limitation required in the pending claims. In the absence of such evidence or reasoning, the rejection should be withdrawn on this basis alone.

In any case, the Examples section of Bollens is not to make nanoemulsions but compositions which contain liposomes encapsulating an active ingredient which is then

dispersed into the cream, milk, etc. As noted previously, this is what Bollens describes throughout the specification and NOT the preparation of nanoemulsions.

As noted previously by the Applicants, Bollens states that his compositions can be microemulsions. (Col. 3, line 49). Bollens never teaches or suggests that his compositions can be nanoemulsions. Therefore, Bollens does not provide any guidance to select a water-soluble nonionic polymer which is present in a nanoemulsion thickening effective amount. Applicants again point out that the “effective amount” limitation is a real limitation which must be disclosed in the prior art for the pending claims to be unpatentable. *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 67 U.S.P.Q.2d 1191 (Fed. Cir. 2003) (“effective amounts” are not necessarily disclosed by prior art compositions containing the claimed active ingredient; the desired effect must be achieved).

In view of the above, Bollens does not anticipate or render obvious the claimed invention.

Regarding the rejections based on US 990, this reference discloses compositions containing polyethylene/polypropylene copolymer surfactants such as, for example, poloxamers. Such surfactants (1) have much lower molecular weight than is required by the claims (for example, Poloxamer 231 has a molecular weight of 2807 and Poloxamer 284 has a molecular weight of 3698—see col. 2, lines 55-64); and (2) are surfactants, not effective thickening agents.

Because the claimed invention requires the presence of homopolymers and copolymers of ethylene oxide having a molar mass equal to or greater than 10,000 g/mol, US 990, which merely discloses the presence of low molecular weight compounds, cannot teach or suggest the present invention. Moreover, US 990 does not teach or suggest the presence of a nanoemulsion thickening effective amount of the claimed polymers as required by the claims (Applicants again refer the Examiner to a discussion of “effective amounts” in

*Abbott Laboratories* cited above). Because US 990 does not disclose a nanoemulsion thickening effective amount of the claimed polymers but rather merely discloses the presence of lower molecular weight compounds in a surfactant effective amount, the reference cannot teach or suggest the claimed invention for this reason as well.

Furthermore, Applicants submit data in the form of a Rule 132 declaration that demonstrates that US 990 polymers were unable to thicken and stabilize nanoemulsion compositions relative to a poly(ethylene oxide) having a molar mass of 300,000 g/mol according to the claimed invention. More specifically, the composition of Example 1 from the specification was compared to two compositions where the poly (ethylene oxide) having a molar mass of 300,000 g/mol was replaced with polyoxamer 338 (comparative example A) or polyoxamer 403 (comparative example B). The results of the analyses are presented in paragraphs 7, 8 and 9. In conclusion, “These results show that unlike compositions A and B, compositions according to the present invention provide thickened nanoemulsions which remain stable over time and over various temperature ranges.”

Accordingly, US 990 does not anticipate or render obvious the claimed invention.

In view of the above, Applicants respectfully submit that the rejections under 35 U.S.C. §§102 and 103 based upon Bollens and US 990 are improper and should be withdrawn.

Regarding the remaining rejections under § 103 rejections, these rejections are also improper and should be withdrawn. None of the references, alone or in combination, would lead one skilled in the art to add the claimed polymers to a nanoemulsion in a nanoemulsion thickening effective amount. FR 027, US 150, US 960, Suzuki and EP 460 neither teach nor suggest the claimed nonionic polymers. Moreover, these references neither teach, suggest nor recognize any benefits associated with adding the claimed water-soluble nonionic

polymers to nanoemulsions. Thus, these references cannot teach or suggest adding a nanoemulsion thickening effective amount of such polymers to nanoemulsions.

None of the remaining references relate to nanoemulsions, so they cannot compensate for these critical deficiencies. None of the remaining references teaches or suggests anything about nanoemulsions, let alone adding the claimed water-soluble nonionic polymers to nanoemulsions in a nanoemulsion thickening effective amount or any benefits associated from such addition. Accordingly, none of these references would motivate one skilled in the art to modify nanoemulsions in any way, let alone by adding the claimed nonionic polymers to nanoemulsions in a nanoemulsion thickening effective amount with the expectation that useful and acceptable nanoemulsions would result, particularly transparent, thickened nanoemulsions such as those having the characteristics set forth in claims 39-42.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Finally, Applicants respectfully submit that the rejection of claim 41 under 35 U.S.C. § 112 as being duplicative of claim 40 has been rendered moot by the above amendments to claim 41, and that this rejection should be withdrawn.

Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
FLORENCE L'ALLORET, ET AL. : EXAMINER:  
SERIAL NO: 09/903,768 :  
FILED: JULY 13, 2001 : GROUP ART UNIT: 1714  
FOR: NANOEMULSION CONTAINING :  
NONIONIC POLYMERS, AND ITS USES

DECLARATION UNDER 37 C.F.R. §1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Florence L'Alloret who deposes and states that:

1. I am an inventor of 09/903,768 and am familiar with the prosecution history thereof.
2. I have been employed by L'Oréal for 6 years as a skin care engineer in the field of skin care formulation.
3. The following experiments were performed by me or under my supervision.
4. The following experiments demonstrate that formulating an oil-in-water nanoemulsion with an oily phase, at least one amphiphilic lipid and at least one water-soluble nonionic polymer results in stable compositions compared to compositions prepared with polyoxamer surfactants as described in U.S. patent no. 6,464,990.
5. The composition of Example 1 was compared to two compositions where the poly(ethylene oxide) having a molar mass of 300,000 g/mol was replaced with polyoxamer 338 (comparative example A) or polyoxamer 403 (comparative example B). The compositions

were prepared and assessed according to the description provided in the present application, e.g., on pages 33-34.

6. The compositions compared are:

	Ex. 1	A	B
A PEG 400 isostearate	4.5%	4.5%	4.5%
Disodium acylglutamate	0.5 %	0.5 %	0.5 %
Isopropyl myristate	5 %	5 %	5 %
Isoscetyl stearate	10 %	10 %	10 %
B Dipropylene glycol	10 %	10 %	10 %
Glycerol	5 %	5 %	5 %
Distilled Water	32.5 %	32.5 %	32.5 %
C Poly(ethylene oxide) having a molar mass of 300,000 g/mol	3 %	0	0
Synperonic PF/F108 (POLYOXAMER 338)	0	2.5 %	0
Pluronic P123 (Polyoxamer 403) having a molar mass of 5838 g/mol	0	0	3 %
Distilled water	29.5%	30 %	29.5%

7. The composition of Example 1 is transparent and has a turbidity of 288 NTU, a viscosity of 1.1 Pa.s (at 200 s<sup>-1</sup>). The viscosity remains stable at several temperatures (4°C and 45°C) and stable over time.

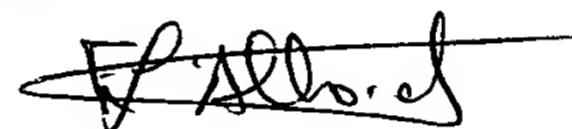
8. Composition A has a viscosity of 1.86 Pa.s at 4°C and 0.98 Pa.s at 45°C (at 200 s<sup>-1</sup>). Therefore, the viscosity at 45°C was 54% lower than the viscosity at 4°C and demonstrates that composition A does not remain stable when the temperature is varied. Furthermore, composition A at 4°C becomes cloudy over time.

9. Composition B has a viscosity of 0.02 Pa.s (at 200 s<sup>-1</sup>). Therefore, the poloxamer does not thicken the composition in contrast to the polymers employed in Example 1.

10. These results show that unlike compositions A and B, compositions according to the present invention provide thickened nanoemulsions which remain stable over time and over various temperature ranges.

11. That the undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information are believed to be true. Further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Signature



Date 31.08.04